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| APPLICATION NO.                             | F                     | ILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.       | CONFIRMATION NO |
|---|-----------------------|------------|----------------------|---------------------------|-----------------|
| 10/088,661                                  | 10/088,661 07/19/2002 |            | Nobuyuki Miyasaka    | 14875-103US1              | 2830            |
| 26161                                       | 7590                  | 02/14/2006 |                      | EXAM                      | INER            |
| FISH & RICHARDSON PC                        |                       |            |                      | WOODWARD, CHERIE MICHELLE |                 |
| P.O. BOX 1022<br>MINNEAPOLIS, MN 55440-1022 |                       |            |                      | ART UNIT                  | PAPER NUMBER    |
| •   | <b>,</b>              |            |                      | 1647                      | <del>.</del>    |

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | Application No.   | Applicant(s)   |  |  |  |
|--|---|--|--|--|--|
|  | 10/088,661  | MIYASAKA ET AL.  |  |  |  |
| Office Action Summary  | Examiner  | Art Unit   |  |  |  |
|  | Cherie M. Woodward  | 1647   |  |  |  |
| The MAILING DATE of this communication Period for Reply  | appears on the cover sheet wit  | th the correspondence address  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR RE WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CF after SIX (6) MONTHS from the mailing date of this communication - If NO period for reply is specified above, the maximum statutory pe - Failure to reply within the set or extended period for reply will, by st Any reply received by the Office later than three months after the m earned patent term adjustment. See 37 CFR 1.704(b). | G DATE OF THIS COMMUNIC R 1.136(a). In no event, however, may a re i. riod will apply and will expire SIX (6) MON tatute, cause the application to become AB. | CATION.  apply be timely filed  THS from the mailing date of this communication.  ANDONED (35 U.S.C. § 133). |  |  |  |
| Status   |   |  |  |  |  |
| 1) Responsive to communication(s) filed on 1   | 9 July 2002.  |  |  |  |  |
| ·—   | This action is <b>FINAL</b> . 2b)⊠ This action is non-final.  |  |  |  |  |
| 3) Since this application is in condition for allo   |   |  |  |  |  |
| closed in accordance with the practice und   | er Ex parte Quayle, 1935 C.D.   | . 11, 453 O.G. 213.  |  |  |  |
| Disposition of Claims  |   |  |  |  |  |
| 4) ⊠ Claim(s) <u>9-25</u> is/are pending in the applicate 4a) Of the above claim(s) is/are with 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☒ Claim(s) <u>9-25</u> are subject to restriction and  | drawn from consideration.   |  |  |  |  |
| Application Papers   |   |  |  |  |  |
| 9) The specification is objected to by the Exam 10) The drawing(s) filed on is/are: a) Applicant may not request that any objection to Replacement drawing sheet(s) including the co 11) The oath or declaration is objected to by the   | accepted or b) objected to be the drawing(s) be held in abeyan rrection is required if the drawing(   | ce. See 37 CFR 1.85(a).<br>(s) is objected to. See 37 CFR 1.121(d).  |  |  |  |
| Priority under 35 U.S.C. § 119   |   |  |  |  |  |
| 12) Acknowledgment is made of a claim for force a) All b) Some * c) None of:  1. Certified copies of the priority docum 2. Certified copies of the priority docum 3. Copies of the certified copies of the application from the International Bu * See the attached detailed Office action for a   | nents have been received.<br>nents have been received in A<br>priority documents have been<br>reau (PCT Rule 17.2(a)).  | pplication No received in this National Stage  |  |  |  |
| Attachment(s)  1) X Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SE   | Paper No(s  | iummary (PTO-413)<br>s)/Mail Date<br>nformal Patent Application (PTO-152)                                    |  |  |  |

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## **DETAILED ACTION**

## Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- Group I, claims 9 and 13, in part, as drawn to a method of preventing or treating aberrant growth or inflammation comprising identification of a subject and increasing the amount or function of a p21CIP1 protein in the joint of a subject.
- Group II, claims 10 and 14, in part, as drawn to a method of administering a p21CIP1 protein.
- Group III, claims 11 and 15, in part, as drawn to a method of administering DNA encoding a p21CIP1 protein to a subject (gene therapy).
- Group IV, claims 12 and 16, in part, as drawn to a method of administering a compound.
- Group V, claims 17-24, drawn to a method of screening for a compound that inhibits aberrant growth of inflammation or synovial tissue.
- Group VI, claims 13-16, in part, and 25, as drawn to a method of treating rheumatoid arthritis in a subject.
- 2. The inventions listed as Groups I and VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: claim 1 lacks novelty under PCT Article 33(2) as being anticipated by Sugiyama *et al.*, Localisation of apoptosis and expression of apoptosis related proteins in the synovium of patients with rheumatoid arthritis. Ann Rheum Dis 1996 July 55(7):442-9. Sugiyama *et al.*, disclose a apoptosis specific morphology and expression of p21/CIP1 in rheumatoid arthritis synovial tissue (see entire article). The Sugiyama *et al.*, reference meets the limitations recited in claim 1. Restriction is required under 35 U.S.C. 121 and 372.

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3. Applicant is advised that the reply to this requirement to be complete must include an election of

the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the

inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named

inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of

inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37

CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should

be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can

normally be reached on Monday - Thursday 9:00am-7:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor,

Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where

this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application

Information Retrieval (PAIR) system. Status information for published applications may be obtained

from either Private PAIR or Public PAIR. Status information for unpublished applications is available

through Private PAIR only. For more information about the PAIR system, see http://pair-

direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

**CMW** 

BRENDA BRUMBACK SUPERVISORY PATENT EXAMINER

TECHNOLOGY CENTER 1600